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37211 7590 09/18/2009 BASCH & NICKERSON LLP			EXAMINER	
1777 PENFIEL	LD ROAD		WINTER, JOHN M	
PENFIELD, NY 14526			ART UNIT	PAPER NUMBER
			3685	
			NOTIFICATION DATE	DELIVERY MODE
			09/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Application No. Applicant(s) 09/919 275 PAPIER ET AL. Office Action Summary Examiner Art Unit JOHN M. WINTER 3685 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 11 February 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-24 and 31-36 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-24 and 31-36 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner, Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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DETAILED ACTION

Status of Claims

The Applicants request filed on February 11, 2009 is hereby acknowleged esponse filed on 28 March 2005. Claims 1-24 and 31-36 remain pending and are presented for examination.

A request for continued examination under 37 CFR 1.111 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal, the appeal has been withdrawn pursuant to 37 CFR 1.111 and prosecution in this application has been reopened pursuant to 37 CFR 1.111.

Response to Arguments

- Applicant's arguments filed February 11, 2009 have been fully considered but they are not persuasive.
- 3. Applicant argues that Wilk's automated diagnostic system teaches away from the visual aid intended by the present invention. Examiner submits, however, that the language of claim 1 includes a diagnostic engine that automatically identifies a subset of diagnoses that are consistent with the characteristics. Examiner submits that Wilk, along with Bodick, disclose this and that it would have been obvious that a medical professional would have used the systems of Wilk and Bodick as an aid rather than a substitute for a diagnosis. Wilk states that "even if the patient eventually sees a physician for confirming the diagnosis, the computer input will facilitate the physician's evaluation of the patient's

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condition and reduce the amount of time necessary for the physician to examine the patient" (Col. 3, lines 64-68), thus supporting the idea that the invention may be used as an aid rather than a final diagnosis.

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- 4. Applicant further argues that Wilk does not disclose the storage of images in an image database, separate from a knowledgebase. Examiner respectfully disagrees and submits that Wilk discloses a memory that stores entire images related to different diseases (Col. 2, lines 46-56; Col. 7, lines 19-24) stored at a dermatological diagnosis and treatment facility and this is being interpreted by the examiner as an image database. Wilk also discloses a computer that compares the image of a patient with the previously stored images and overlaying the sections with sections of the stored images (Col. 2, lines 50-56); and to derive a diagnosis as to the patient's condition (Col. 4 line 65-Col. 5 line 3). This seems to suggest that the computer processing or knowledgebase is separate from the stored images. Furthermore, Bodick et al disclose a knowledgebase that includes both textual and pictorial information (Col. 2, lines 30-61; Col. 3, lines 20-34 and 44-48; Col. 6, lines 15-22; Col. 12 line 50-Col. 13 line 11; Col. 15 line 62-Col. 16 line 3).
- 5. Applicant further argues that Wilk fails to disclose a user interface to solicit a plurality of descriptive characteristics. Examiner respectfully disagrees and submits that Wilk discloses the use of a keyboard for entry of information such as known medical history and conditions which is also used in diagnosing the patient (Col. 7, lines 3-8).
- Applicant further argues that Bodick fails to disclose automatically identifying,
 from a plurality of possible diagnoses, a subset including a plurality of diagnoses that are

consistent with the characteristics. Examiner respectfully disagrees and submits that Bodick et al disclose that information on specific diseases may be requested, such as a request for retrieval of all cases having specified features or a request for all cases in which a particular disease was diagnosed and Side by side presentation of pictorial images and display of text information relating to different diseases or features would assist evaluation and diagnosis (Col. 5, lines 40-50). This passage seems to suggest that a concurrent display of a plurality of images.

7. Applicant further argues that there is no motivation to suggest the references of Wilk and Bodick et al. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPO2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Wilk discloses the use of a computerized system to aid in the diagnosis of a patient condition and Wilk discloses that the system may be used by a physician as input that will facilitate the physician's evaluation of the patient's condition and reduce the amount of time necessary for the physician to examine the patient (Col. 3, lines 64-68). Bodick et al also disclose a system used as an aid to a medical professional for diagnosing patient conditions and suggest that such a system would benefit a physician since specialists often need assistance in diagnosing a medical condition or disease based upon his clinical observations of a

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patient (Col. 2, lines 3-7). Examiner submits that, based on these teachings among others, one having ordinary skill in the art would have been motivated to combine the teachings of the references to Wilk and Bodick et al.

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- 8. As per Claims 6-11, applicant argues that Bodick et al fail to disclose a diagnostic image stack. Examiner respectfully disagrees and submits that Bodick et al disclose a diagnostic image stack (Figure 26) comprising a subset of a plurality of images, each image being associated with a common diagnosis and an index into the subset of images wherein the index is independent of the common diagnosis including a display of associated characteristics of diagnoses when a user selects a portion of an image (Figure 26; Col. 2, lines 30-45; Col. 5, lines 40-48; Col. 6, lines 34-46; Col. 20, lines 15-39). More specifically, Bodick et al disclose the display of images associated with various diseases in an image stack or side by side presentation (Col. 2, lines 30-45; Col. 5, lines 40-48; Col. 6, lines 34-46).
- 9. As per claim 12, applicant argues that Wilk cannot teach what has been alleged since it would require a user interface and characteristics that are not taught by Wilk. Examiner respectfully disagrees and notes that Wilk does disclose a user interface as discussed above.
- 10. With regard to claims 16-18 and 20-21, examiner has cited an additional reference to support the previous Official Notice statement. Examiner also submits that the citation of the reference in the rejection below has been added as evidence to substantiate the prior Official Notice statement, does not result in a new issue, and therefore this action will be made Final.

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11. With respect to claims 19, 22-23 and 28, Bodick et al disclose that it will be apparent that the presentation of pictorial images in conjunction with textual data which relate to those images and assist in the evaluation of them is valuable in any area where the appearance of an object under study/examination is of critical importance (Col. 9, lines 42-56). Thus, examiner submits that it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and utilize the invention for any purpose as suggested by Bodick et al for the cognitive process of diagnosis.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3, 4, and 31-36 are rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Based on Supreme Court precedent (See also *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)) and recent Federal Circuit decisions, a §101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. In addition, the tie to a particular apparatus, for example, cannot be mere extra-solution activity. See *In re Bilski*, 88 USPO2d 1385 (Fed. Cir. 2008).

An example of a method claim that would not qualify as a statutory process would be a claim that recited purely mental steps.

To meet prong (1), the method step should positively recite the other statutory class (the thing or product) to which it is tied. This may be accomplished by having the claim positively recite the machine that accomplishes the method steps. Alternatively or to meet prong (2), the method step should positively recite identifying the material that is being changed to a different state or positively recite the subject matter that is being transformed.

In this particular case, claim 3 fails prong (1) <u>because the "tie" (e.g. knowledge database)</u> is representative of extra-solution activity. Additionally, the claim(s) fail prong (2) because the method steps do not transform the underlying subject matter to a different state or thing.

Claims 4 and 31-36 are either dependant up[on claim 3 or contain similar limitations and are rejected for a t least the same reasons.

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-15, 19, 22-24, 31-32 and 35 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk, U.S. Patent No. 5,437,278 in view of Bodick et al, U.S. Patent No. 4,945,476.

As per Claims 1, 3, 5 and 31 Wilk discloses a system to aid in a visual diagnostic process, comprising:

a computer system; an image database, accessible by said computer system; (Col. 1, lines 55-62; Col. 2, lines 46-56; Col. 6, lines 15-26);

a knowledge database, accessible by said computer system, cross-referenced to said image database, for the purpose of assisting in the diagnostic process, said knowledge database including a plurality of findings-diagnosis links representing relationships between findings and diagnoses; (Col. 1, lines 55-58; Col. 2, lines 25-32; Col. 4, lines 55-60);

a user-interface attached to said computer system to solicit, from a the user, a plurality of descriptive characteristics of a sample requiring diagnosis; (Col. 4, lines 48-54; Col. 7, lines 3-8);

a diagnostic engine operating in said computer system, responsive to said descriptive characteristics, (Col. 1, lines 59-62; Col. 2, lines 27-33; Col. 4 line 65-Col. 5 line 3);

Wilk, however, fails to disclose wherein said characteristics of the sample are employed by said engine to automatically identify, using the findings diagnosis links, a subset including a plurality of possible diagnoses that are consistent with the characteristics; and Art Unit: 3685

using the subset of diagnoses, automatically reorganizing an information space of said image database for concurrent presentation on said user-interface of a plurality of images representing the subset of possible diagnoses for user review via the user-interface. Bodick et al discloses wherein said characteristics of the sample are employed by said engine to automatically identify, using the findings diagnosis links, a subset including a plurality of possible diagnoses that are consistent with the characteristics; and using the subset of diagnoses, (Col. 2, lines 30-61; Col. 3, lines 25-30; Col. 5, lines 40-57; Col. 12 line 64-Col. 13 line 11; Col. 20, lines 15-38; Col. 24, lines 28-48) automatically reorganizing an information space of said image database for concurrent presentation on said user-interface of a plurality of images representing the subset of possible diagnoses for user review via the user- interface. (Col. 2, lines 30-61; Col. 3, lines 25-30; Col. 5, lines 40-48; Col. 6, lines 15-22; Col. 20, lines 15-38). Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and incorporate the ability to identify a subset of possible diagnoses based on a sample of characteristics and further to display the images or other data related to the subset of diagnoses as taught by Bodick et al. Bodick et al provides motivation by indicating that these features would benefit doctors or physicians by assisting them in searching information that would help them in diagnosing a medical condition (Col. 1, lines 10-16; Col. 2, lines 1-8). Examiner notes that a wherein clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. (Texas Instruments Inc. v. International Trade Commission 26, USPO2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPO2d 1431

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(Fed. Cir. 2002); Amazon.com Inc. v. Barnesandnoble.com Inc., 57 USPQ2d 1747 (CAFC 2001).

As per Claim 2, Wilk fails to disclose a dynamic diagnostic engine to reorganize the information space upon modification of one of a plurality of descriptive characteristics. Bodick et al disclose a dynamic diagnostic engine to reorganize the information space upon modification of a descriptive characteristics by the user (Col. 2, lines 50-62; Col. 5, lines 50-57; Col. 20, lines 15-39). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and include a dynamic diagnostic engine such as that described by Bodick et al in order to assist the doctor in diagnosing a particular medical condition and allow the doctor to dynamically modify a characteristic in an effort to view all proposed diagnoses that may be related.

As per Claim 4, Wilk fails to disclose a dynamic diagnostic engine to reorganize the information space upon modification of one of a plurality of descriptive characteristics. Bodick et al disclose a dynamic diagnostic engine to reorganize the information space upon modification of a descriptive characteristic (Col. 2, lines 50-62; Col. 5, lines 50-57; Col. 20, lines 15-39). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and include a dynamic diagnostic engine such as that described by Bodick et al in order to assist the doctor in

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diagnosing a particular medical condition and allow the doctor to dynamically modify a characteristic in an effort to view all proposed diagnoses that may be related.

As per Claims 5 and 24, Wilk discloses a system for reducing diagnostic uncertainty using cross-referenced knowledge and image databases, comprising:

- a user-interface to solicit a plurality of characteristics of diagnoses from a user
 (Col. 4, lines 48-54; Col. 7, lines 3-8);
- a diagnostic engine, wherein said characteristics of diagnoses are employed to
 automatically identify, from a plurality of possible diagnoses for which data is stored in
 the knowledgebase, a diagnosis from the knowledgebase that is consistent with the
 characteristics (Col. 1, lines 59-62; Col. 2, lines 27-33; Col. 4 line 65-Col. 5 line 3).

Wilk, however, fails to disclose identifying a subset of diagnoses and using the subset of diagnoses to reorganize an information space of said image database for concurrent presentation of a plurality of images for user review via the user-Interface.

Bodick et al disclose a computerized aid to the process of medical diagnosis and teach a diagnostic engine that returns a subset including a plurality of diagnoses responsive to characteristics entered by a user (Col. 2, lines 30-61; Col. 3, lines 25-30; Col. 5, lines 40-57; Col. 12 line 64-Col. 13 line 11; Col. 20, lines 15-38; Col. 24, lines 28-48). Bodick et al further disclose automatically reorganizing an information space for concurrent presentation of a plurality of images or user review (Col. 2, lines 30-61; Col. 3, lines 25-30; Col. 5, lines 40-48; Col. 6, lines 15-22; Col. 20, lines 15-38). Bodick et al further disclose wherein the plurality of characteristics of diagnosis include exposure to certain

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materials and morphology (Col. 26 line 30-Col. 35 line 30). Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and incorporate the ability to identify a subset of possible diagnoses based on a sample of characteristics and further to display the images or other data related to the subset of diagnoses as taught by Bodick et al. Bodick et al provides motivation by indicating that these features would benefit doctors or physicians by assisting them in searching information that would help them in diagnosing a medical condition (Col. 1, lines 10-16; Col. 2, lines 1-8).

As per Claims 6-11, and 31 Wilt fails to disclose a diagnostic image stack comprising a subset of a plurality of images, each image being associated with a common diagnosis, wherein each image is displayed to depict stages of a disease progression or a plurality of images associated with a particular diagnosis or wherein an image presented to the user includes a display of associated characteristics of diagnoses when a user selects a portion of an image being displayed. Bodick et al disclose a diagnostic image stack (Figure 26) comprising a subset of a plurality of images, each image being associated with a common diagnosis and an index into the subset of images wherein the index is independent of the common diagnosis including a display of associated characteristics of diagnoses when a user selects a portion of an image (Figure 26; Col. 2, lines 30-45; Col. 5, lines 40-48; Col. 6, lines 34-46; Col. 20, lines 15-39). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and include the above features as taught by Bodick et al in an

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effort to facilitate the physicians diagnosis of a medical condition by presenting an easily understandable means for enabling the physician to browse different images associated with a particular diagnosis. Bodick et al further discloses a plurality of images associated with a particular diagnosis, however, fail to further disclose images depicting disease progression. Examiner submits, however, that this would have been obvious in view of the teachings of Bodick et al in an effort to offer a plurality of images to the physician in order to determine the nature of the particular disease associated with the current patient.

As per Claim 12, 35 and 36, Wilk further discloses wherein the diagnostic engine uses the characteristics of diagnoses to perform a pattern recognition operation on the knowledge database and to Identify diagnoses with matching characteristics (Col. 1, lines 59-62; Col. 2, lines 27-33; Col. 4 line 65-Col. 5 line 3).

As per Claims 13-14, Wilk further discloses wherein the system is applicable to and includes characteristics of diseases that have a dermatological manifestation or visible to the unaided human eye (Col. 2, lines 35-45).

As per Claim 15, Wilk further disclose wherein the system for reducing diagnostic uncertainty is applicable to and includes characteristics of diseases that are determined based upon a finding determined by mechanical examination means (Figure 1; Col. 2, lines 10-16).

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As per Claims 19 and 22-23, Wilk and Bodick et al fail to specifically disclose wherein the system for reducing diagnostic uncertainty is applicable to and includes characteristics of oral medications. Bodick et al, however, disclose that it will be apparent that the presentation of pictorial images in conjunction with textual data which relate to those images and assist in the evaluation of them is valuable in any area where the appearance of an object under study/examination is of critical importance. Thus, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the system of Wilk and utilize the invention for any purpose as suggested by Bodick et al for the cognitive process of diagnosis.

 Claims 16-18, 20-21 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk, U.S. Patent No. 5,437,278 in view of Bodick et al, U.S. Patent No. 4,945,476 and Kehr et al, U.S. Patent Application Publication No. US 2003/0036683 A1.

As per Claims 16-18, 20-21 and 33-34, Wilk and Bodick et al fail to disclose wherein the user interface to solicit a plurality of characteristics includes at least one symptom represented as an icon. Examiner takes Official Notice, however, that representing items with an icon in a user interface is well known in the art and it would have been obvious to one having ordinary skill in the art at the time of applicant's invention to use icons as a matter of convenience for the user. In support of this Official Notice statement, examiner refers to the teachings of Kehr et al, wherein Kehr et al disclose the use of icons to

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symbolize various medical information and characteristics associated with a patient (paragraph 362). Accordingly, examiner submits that it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the systems of Wilk and Bodick et al and include the use of icons to represent to symbolize various characteristics or symptoms related to the health of the patient as taught by Kehr et al. As stated previously, one would have been motivated to use icons since they were well known in the art at the time of applicant's invention as a means to conveniently represent information in a user interface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN M. WINTER whose telephone number is (571)272-6713. The examiner can normally be reached on M-F 8:30-6, 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Calvin Hewitt can be reached on (571) 272-6709. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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JMW

/EVENS J. AUGUSTIN/

Primary Examiner, Art Unit 3621